



U.S. Department of Justice

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February 26, 2018

Paul T. Ferrell, Jr.
Farrell, Bailey & Tweel LLP
419 Eleventh Street
Huntington, WV 25724-2389
Sent via e-mail: paul@greeneketchum.com

Re: *In Re: National Prescription Opiate Litigation.*
N.D. Ohio Case No. 1:17-MD-2804

Dear Mr. Ferrell:

The United States Department of Justice ("DOJ") is in receipt of the February 2, 2018 Order issued in the above-captioned case and your letter dated February 13, 2018, in which you requested disclosure of official DOJ information. Specifically, you asked for ARCOS information from the United States Drug Enforcement Administration ("DEA") to determine:

1. Manufacturer market share of prescription opiates;
2. Distributor market share of prescription opiates; and
3. Allocation of damages.

Your request seeks "data which establishes which pills, made by which manufacturers, were distributed by which distributors, to which retailers beginning in 2006." By this request, I understand that you seek to identify non-party manufacturers whom you believe should be part of the settlement process and to identify possible fault by DEA registrants by comparing communities that received the most prescription opiates with CDC statistics related to opioid addition, abuse, morbidity, and mortality.

As discussed in detail below, *see infra* p. 6-8, pursuant to DOJ's *Touhy* regulations the DEA agrees that it is in the public interest to provide a limited authorization to release the names of all manufacturers in each state who comprise 95% or more of the market share for certain opioids; a spreadsheet of data exported from the ARCOS database for each of the 50 states and Puerto Rico with transaction data for 2012 and 2013; and information explaining the native format of the ARCOS database, the fields in the database, the size of the database, and the software used to

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manipulate the database—provided that the release of this information is covered by an acceptable protective order.

The DOJ and the DEA are committed to combating the epidemic of prescription drug abuse and appreciate the opportunity to assist in this litigation. In order to share information to assist you in your efforts, the DOJ must follow the law and policies that govern disclosure of official DOJ information by federal employees and agencies, including the DEA. *See* 28 C.F.R. § 16.21-.29 (“*Touhy* regulations”). The *Touhy* regulations apply, *inter alia*, in situations such as this, where the United States is not a party to the proceeding. Under those regulations, current and former DEA employees are prohibited from disclosing official information absent express authorization from the DOJ. 28 C.F.R. § 16.22(a).

The Supreme Court has long recognized the authority of federal agencies to regulate the disclosure of information by their employees. *U.S. ex rel. Touhy v. Ragen*, 340 US. 462 (1951). In *Touhy*, the Supreme Court held that a federal employee could not be held in contempt for refusing to produce subpoenaed documents, where his refusal was based on regulations prohibiting the disclosure of official information without prior authorization. *Id.* at 468. Nor did such regulations invade the authority of the Courts to determine the admissibility of evidence. *Id.* at 468-70.

Pursuant to 28 C.F.R. § 16.22, I am the official responsible for consulting with the DEA and authorizing any disclosure in this case in response to your request. Federal regulations require me to consider whether disclosure is appropriate under the applicable rules of procedure and law concerning privilege. 28 C.F.R. § 16.26(a). I am prohibited from releasing official information if disclosure would:

1. Violate a specific statute or regulation;
2. Reveal classified information;
3. Reveal a confidential source or informant;
4. Reveal investigative techniques or investigatory records compiled for law enforcement purposes; or
5. Reveal trade secrets without the owner’s consent.

28 C.F.R. § 16.26(b).

Many of these factors apply to your request for information from the ARCOS database. These include, but are not limited to, the following:

1. Law-Enforcement-Sensitive Information

While we are committed to sharing information, such disclosures cannot be to the detriment of DEA’s ongoing or future law enforcement investigations, enforcement actions, or prosecutions. ARCOS data is compiled for regulatory and law enforcement purposes, and disclosing certain ARCOS data could interfere with ongoing and future law enforcement activities. 27 C.F.R. § 16.26(b)(5).

The Controlled Substances Act authorizes the Attorney General to “cooperate with local, State, tribal, and Federal agencies concerning the traffic in controlled substances and in suppressing the abuse of controlled substances.” 21 U.S.C. § 873(a). Pursuant to § 873(a)(1), the Attorney General may “arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances.” Similarly, under § 873(a)(6)(C), the Attorney General may “assist State, tribal, and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by...establishing cooperative investigative efforts to control diversion.” The Attorney General has delegated this authority to the DEA Administrator. 28 C.F.R. § 0.103(a)(1) and (2) (Administrator may “release information obtained by DEA and DEA investigative reports to Federal, State, and local prosecutors, and State licensing boards, engaged in the institution and prosecution of cases before courts and licensing boards related to controlled substances.”). ARCOS is an important tool in DEA’s law enforcement and regulatory missions and must be protected for DEA to fulfill its purpose. For that reason, access to ARCOS is restricted to DEA employees who have appropriate security clearances and who have a need to know any sought information. The ARCOS database is housed at DEA, and no third parties are given direct access to the database.

The DEA shares data extracted from ARCOS on a case-by-case basis with its federal and state law enforcement and regulatory counterparts who have a need to know and are operating in coordination with DEA for investigative purposes. This practice is consistent with longstanding DOJ policy instructing agencies not to provide access to information that relates to ongoing investigative or enforcement activities. *See* 40 Op. Att’y Gen. 45, 56 (1941). This practice also recognizes that it takes time to develop investigations and prosecutions from ARCOS leads. Certain information contained in ARCOS is, therefore, the subject of or related to numerous ongoing investigations and prosecutions.

The Sixth Circuit recently held that the FBI properly withheld information under the law-enforcement FOIA exemption, finding that the release of certain demographic data could have revealed law-enforcement priorities and methodologies, that the FBI provided reasonably segregated portions of the data, and that the requester’s initial proposal inadequately protected law-enforcement-sensitive information. *ACLU of Mich. V. FBI*, 734 F.3d 460 (6th Cir. 2013); *see also NAACP v. ACUSport, Inc.*, 271 F. Supp. 2d 435 (E.D.N.Y. 2003) (allowing limited disclosure of ATF’s Firearms Tracing System database in public nuisance lawsuit, but noting that “linking a traced gun to a specific crime location, as well as identifying data concerning the firearms distributor and dealer,” is law-enforcement-sensitive and, and such, should be subject to a strong protective order and limited to a period of three years).

2. Trade Secrets

The DEA must protect the commercial information of innocent parties. It is the policy of the United States government—enforced by the threat of criminal sanction—to protect as confidential the business records commercial enterprises are compelled to give the government. *See* 18 U.S.C. § 1905 (“Whoever, being an officer or employee of the United States or of any department or agency thereof . . . publishes, divulges, discloses, or makes known in any manner

... any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined under this title, or imprisoned not more than one year, or both; and shall be removed from office or employment.”). For this reason, the *Touhy* regulations prohibit the disclosure of official information that would reveal trade secrets without the owner’s consent. See 28 C.F.R. § 16.26(b)(5).

The consideration of trade secrets under the *Touhy* regulations is similar to FOIA’s exemption 4, which exempts from disclosure both trade secrets and confidential commercial information. 5 U.S.C. § 552(b)(4). Under FOIA exemption 4, data is “confidential commercial information” if “disclosure of the information is likely to: (1) impair the Government’s ability to obtain necessary information in the future or (2) cause substantial harm to the competitive position of the person from whom the information was obtained.” *Nat’l Parks & Conservation Ass’n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974) (explaining exemption may be invoked for benefit of person who has provided commercial information if public disclosure is likely to cause substantial harm to competitive position). Federal courts have repeatedly recognized the government’s right to invoke FOIA exemption 4 in defense to a subpoena, when the data in its possession was reported to the government and public disclosure would harm the competitive interests of the reporting party. See, e.g., *N.H. Right to Life v. United States HHS*, 778 F.3d 43 (1st Cir. 2015); *Am. Mgmt. Servs. V. Dep’t of the Army*, 703 F.3d 724 (4th Cir. 2013).

In this case, the ARCOS database contains over 80,000,000 transactions per year of controlled substances. None of the Registrants who provided ARCOS information to the DEA have consented to its release at this time. For any manufacturer or distributor, the data contained in ARCOS would establish a complete customer list including location and amount of sales. Disclosure of this data could cause substantial competitive harm by, for example, giving entities information about their competitors’ business strategies, market shares, and inventory levels. See *Madel v. U.S. Dep’t of Justice*, 784 F.3d 448, 453 (8th Cir. 2015) (holding that disclosure of information from the ARCOS database would “likely” cause “substantial competitive harm”). That harm would fall not only on the industry itself, but also on consumers, who rely on competition to control the costs of prescription medicines.

3. Privacy Act, 5 U.S.C. § 552a

DEA’s authorization to operate ARCOS is subject to numerous privacy requirements. The Privacy Act, 5 U.S.C. § 552a, was enacted “to protect against invasion of an individual’s personal privacy by . . . providing individuals with more control over the gathering, dissemination, and accuracy of [government] agency information about themselves.” *Unger v. District Disclosure Office IRS*, 1:99-CV-698, 2000 U.S. Dist. LEXIS 16064, at *5-6 (N.D. Ohio Sep. 18, 2000). The release of personally identifiable information from a federal system of records without the individual’s consent violates the Privacy Act. *Id.* Here, many of the

ARCOS registrants are individuals, and the Privacy Act therefore protects their information. None of these individuals have consented to the disclosure of their information. Because a wholesale disclosure of ARCOS data could reveal the name and DEA registration number of individual registrants, the DEA is legally obligated to protect their legitimate privacy interests. Indeed, the DEA could subject itself to a private lawsuit by any individual whose data is improperly released outside its routine use. *See, e.g., Kinman v. United States*, No. 1:16-CV-329, 2016 U.S. Dist. LEXIS 169447, at *10 (S.D. Ohio Dec. 7, 2016) (stating that the Privacy Act “provides a private cause of action against federal agencies for violating the Act’s provisions.”); *see also* 5 U.S.C. § 552a(g)(1).

4. Disclosure Facilitating Criminal Activity

Disclosing certain ARCOS information also could facilitate criminal activity. For example, broad disclosure of ARCOS information would allow for strategic planning of large-scale robberies of controlled substances. For example, if a rogue organization can see that large shipments go to a specific pharmacy on a specific day, this allows them to plan and execute robberies based on patterns identified in the data. Over the last ten years the theft and loss of controlled substances have become a major problem. Registrants have specifically acknowledged and informed DEA that publication of such data increases robbery risk.

If released publicly, ARCOS database information could allow criminals to trace the flow of pills. Knowing where manufacturers and distributors are selling the largest number of opioids would allow criminals to target these particular areas of the country and attract more drug seekers who are often associated with collateral crimes that can adversely impact communities.

The same is true at virtually every level of the distribution chain. For example, if criminals know which doctors are prescribing the most opioids, they can target those doctors to facilitate both their own opioid use and drugs sold to their clientele. In other words, while wholesale disclosure might facilitate the MDL plaintiffs’ identification of the “soft spots” in the distribution chain, the very same information, placed in the wrong hands, could expose the public to an even greater crisis. Any disclosure of information from the ARCOS database thus must be subject to a sufficient protective order restricting access to a limited and defined scope of individuals, so as not to exacerbate the opioid crisis by increasing the likelihood that more opioids would reach the hands of the criminals who are facilitating the problem.

5. Available from Other Sources

The requested ARCOS information is available from the Registrants themselves. The individuals and entities who are a party to this lawsuit are the source of the information contained in ARCOS as they report the data to ARCOS. They are the best source of the information and the information is readily in their possession. They are also in the best position to determine whether or not the information is appropriate to disclose and whether its release would cause them competitive harm.

Availability from a more convenient source is a defense to a subpoena served on a non-party—particularly a subpoena served on a government agency that uses the data for law enforcement

purposes. In *Ohio Bureau of Workers' Comp. v. MDL Active Duration Fund, Ltd.*, for example, MDL defendants served a subpoena on the Ohio Inspector General for documents obtained through its investigation of the Bureau of Workers' Compensation. No. 2:05-CV-0673, 2006 U.S. Dist. LEXIS 82560 (S.D. Ohio 2006). The Inspector General moved to quash the subpoena, and the Court granted the motion. One of the factors the Court considered in assessing the law enforcement privilege was whether the materials were available from other sources. *Id.* at *10-11. The MDL defendants made "absolutely no showing that [they] need[ed] to obtain these documents from the Inspector General as opposed to the parties from whom the Inspector General obtained the documents directly." *Id.* at *12. The Court described the subpoena issued by the MDL defendants as, "at best, an effort to obtain, from a single source, documents which might otherwise have to be acquired from different sources." *Id.* at *15. The Court refused to countenance such an effort, where there was a "real risk that disclosure of the documents would either jeopardize [an] investigation or subject the Inspector General, who is not a party to this litigation, to an undue burden in production." *Id.* at *16. Justifying its holding in even stronger terms, the Court said: "The only conceivable justification for this burden would be to make it more convenient for the MDL defendants to obtain documents . . . The Court [did] not believe that the burden [was] justified under these circumstances." *Id.*

The instant matter is no different. Here, the MDL plaintiffs are attempting to obtain from DEA, a single source, government entity that gathers information for law enforcement purposes, all of the data reported by the individual defendants. Nothing prohibits the MDL plaintiffs from obtaining the data from the defendants themselves.

6. Unduly Burdensome

I also note that requests must not place an undue burden on the agency. Here, the DEA would incur an enormous burden to produce the data exactly as the MDL plaintiffs request. Registrants report about 80 million transactions into ARCOS each year. This is approximately one terabyte of data annually. Even when limiting transactions to hydrocodone and oxycodone sales from 2006 to 2017, the ARCOS database houses more than 195,000,000 hydrocodone and more than 141,000,000 oxycodone transactions. As a practical matter, producing the full database in its native format would require an inordinate amount of time. It would also result in the diversion of skilled DEA personnel from their operational and mission-critical duties, and require a significant financial expenditure by DEA.

* * *

After carefully considering your request, consulting with the DEA, applying all of the above factors, and reviewing the relevant procedural and substantive law, I have determined that a limited authorization to provide information to assist the Court and the parties in attempting to reach a settlement in this case is in the public interest. Indeed, I believe that providing the information is consistent with the DOJ's own efforts to combat the devastating opioid crisis that is ravaging families and communities across America.

The DOJ has taken a number of steps to stem the tide of this urgent problem, by, among other things, prosecuting those who overprescribe opioid painkillers and those who flood our streets

with drugs. The DOJ has launched a pilot program to utilize data and focus prosecutions on opioid-related health care fraud including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes. To combat the opioid crisis, the DOJ also has provided millions of dollars in grants to state and local law enforcement agencies to take heroin, methamphetamines, cocaine, and other illicit and diverted drugs off our streets.

I have determined that a limited disclosure of information to you would further purposes complementary to those efforts. However, any disclosure must be pursuant to a protective order that requires, at a minimum, that: (1) all extracted ARCOS data must be kept confidential and may not be publically filed or disclosed; (2) all information remains the property of DOJ/DEA and must be returned or destroyed at the conclusion of litigation; (3) no commercial use of the information is permitted; and (4) certain information may be marked by DEA as “Attorney Eyes Only” and will be kept so restricted. Upon the issuance of such a protective order by the Court, I hereby authorize Demetra Ashley, Acting Assistant Administrator, Diversion Control Division, DEA, to provide the following:

1. An alphabetical list of all manufacturers in each state who comprised 95% or more of the market share for manufacturing oxycodone, hydrocodone, hydromorphone, and fentanyl, including combination products;
2. Excel spreadsheet of data exported from the ARCOS database for each state and Puerto Rico with de-identified transaction data from January 1, 2012 through December 31, 2013, that uses a unique numerical identifier for each buyer and seller for each state. The data fields will include the date of transaction, the buyer’s numerical identifier, the buyer’s state, the first three digits of the buyer’s zip code, the seller’s numerical identifier, the seller’s state, the type of controlled substance, the number of pills, and the dosage gram weight;
3. Specific information about the ARCOS database itself, including its size; native format; data files, records, and fields; and software applications used to view and manipulate the database.

This information will enable the Court and the plaintiffs to determine whether there are any other manufacturing stakeholders who need to be involved in the ongoing settlement proceedings. Further, the de-identified transactional data will allow the MDL plaintiffs to access and analyze a wealth of valuable information, including the date of each transaction, the buyer’s unique identifier, the seller’s unique identifier, the state where the substances were sent, and the first three numbers of the zip code where substances were sent while still protecting the registrants commercial and privacy interests and protecting law-enforcement-sensitive information. Such data will allow the MDL plaintiffs to compare communities which receive the most pills per capita with CDC statistics related to opioid addiction, abuse, morbidity, and mortality. As a result, the MDL plaintiffs will be able to ascertain the prevalence of certain opioids in different communities to fulfill their desire to work to coordinate local, regional, and national abatement plans to achieve maximum efficiency and effectiveness. Finally, this information is both consistent with, and more expansive than, the disclosures DEA has offered to other requestors, including the state Attorneys General, which is justified given the unique circumstances of this

case. Also consistent with DEA's cooperative efforts with state and local governments, if the Court or plaintiffs' review of the data identifies registrants that appear to be engaged in illicit activity, the DEA will consider a subsequent request for information identifying those registrants, consistent with the considerations discussed herein.

Sincerely,



DAVID A. SIERLEJA

First Assistant United States Attorney

Northern District of Ohio

Acting Under Authority Conferred by 28 U.S.C. § 51